HEALTH AND SENIOR SERVICES

DRUG UTILIZATION REVIEW COUNCIL

List of Interchangeable Drug Products

Proposed Amendments: N.J.A.C. 8:71

Authorized By: Drug Utilization Review Council, Robert G. Kowalski, Acting Executive Director

Authority: N.J.S.A. 24:6E-6(b).

Calender reference: April 7, 2003 at 35 N.J.R.1599

Proposal Number: PRN 2003-140

A **public hearing** concerning these proposed amendments will be held on Monday, May 19, 2003, at 10:00 A.M. at the following address:

Room 501, Fifth Floor

Department of Health and Senior Services

Health-Agriculture Building

Trenton, New Jersey

The Council will discuss these products at the June 10, 2003, Drug Utilization Review Council meeting.

Submit comments by May 21, 2003 to:

Robert G. Kowalski, R.Ph.

Acting Executive Director

Drug Utilization Review Council

New Jersey Department of Health and Senior Services

Room 501, P. O. Box 360

Trenton, NJ 08625-0360

609-292-4029

609-984-2218 (FAX)

The agency proposal follows:

Summary

The List of Interchangeable Drug Products is a generic formulary, or list of acceptable generic drugs which pharmacists must use in place of brand-name prescription medicines, passing on the resultant savings to consumers.

Having received notice that the drug product, which is listed in the formulary, is not being manufactured by the indicated manufacturer and, therefore, the product is not available to pharmacies or consumers, the following product is proposed for **deletion** from the List of Interchangeable Drug Products.

PERIOSTAT, Doxycycline hyclate, 20 mg, Capsule, West-ward

Social Impact

Physicians and patients will not be adversely affected by this proposed amendment because there are other manufacturers of this drug product in the Formulary. Some formulations for products listed in the formulary have been reformulated by manufacturers for greater safety and efficacy for patients who need them. Some products proposed for deletion are no longer manufactured because of lack of demand by prescribers and consumers. Some products have been reformulated and the formulations in the Formulary no longer reflect that of the brands referenced.

Economic Impact

Overall, it is anticipated that very few persons will be adversely affected economically by this deletion. Other manufacturers' products are available to prescribers and consumers.

Federal Standards Statement

The proposed amendment to N.J.A.C. 8:71 imposes a standard of practice in New Jersey for licensed pharmacists and prescribers concerning generic drug substitution. The Federal government does not license practitioners to dispense, administer, or prescribe drugs. State law fixes the scope and standards of these authorized practices. The purpose of N.J.A.C. 8:71 was to encourage the substitution of cheaper, but therapeutically equivalent, generic drugs for more expensive brand name drugs. N.J.A.C. 8:71 does require that the pharmaceutical manufacturer demonstrate compliance with "Good Manufacturing Practices" of Title 21 of the United States Code and evidence of a satisfactory inspection by the Food and Drug Administration. These requirements do not exceed the Federal Food, Drug, and Cosmetic Act, Public Law 75-717.

Jobs Impact

The proposed amendment may have a variable effect on job opportunities. As the demand for name brand products decreases due to substitution by a generic equivalent, there may be a decrease in employment opportunities with brand name drug manufacturers. Conversely, the proposed amendment may cause an increase in demand for generic products and have the effect of increasing employment opportunities with generic manufactures. In the case of this amendment, there is no expected effect, since the product deleted is no longer produced by the listed manufacturers.

Agriculture Industry Impact

The proposed amendment will not impact the agriculture industry. The primary purpose of the rule is to regulate the substitution of drugs for use by humans.

Regulatory Flexibility Analysis

The proposed amendment impacts many small businesses, as defined under the Regulatory Flexibility Act, N.J.S.A 52:14B-16 et esq.: specifically, over 2,000 pharmacies and several small generic drug manufacturers which employ fewer than 100 employees.

However, there are no reporting or record keeping requirements for pharmacies, and small generic drug manufacturers have minimal initial reports, and no additional ongoing reporting or record keeping requirements. Further, these minimal requirements are offset by the increased economic benefits accruing to these same small generic businesses due to these proposed amendments.

Smart Growth Impact

The proposed amendment will not impact the achievement of smart growth and implementation of the State Development and Redevelopment Plan. The proposed amendment to N.J.A.C. 8:71 imposes a standard of practice in New Jersey for licensed pharmacists and prescribers concerning generic drug substitution. The primary purpose of the rule is to regulate the substitution of drugs for use by consumers.

Full text of the proposal follows (deletions indicated in brackets [thus]):

The following drugs are listed alphabetically, in a format which represents the name of the substituted brand name drug (reference drug), the generic name of the drug, product, the strength and the dosage delivery system of the drug products, and the names of the approved generic drug's manufacturers:

[PERIOSTAT
Doxycycline hyclate
20 mg Capsule
West-ward]